

A COMPARISON OF DIABETES MANAGEMENT IN A FEDERAL PRISON WITH
THE NATIONAL STANDARDS OF CARE PUBLISHED BY THE ADA IN 1998

Virginia A. Giroux

APPROVED:

Chair: Dr. Carol Ledbetter

Date

Member: Dr. Barbara Sylvia

Date

Member: Susanne Gibbons

Date

APPROVED:

F.G. Abdellah, Ed.D., Sc.D., RN, FAAN
Dean

Date

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ABSTRACT

Diabetes Mellitus (DM) affects 16 million Americans, or 6.2% of the population, and costs the U.S. \$120 billion annually. Specifically, within the Federal Bureau of Prisons (FBOP), DM affects 5.7% of the total inmate population. It is associated with significant morbidity and mortality. It is the leading cause of blindness, non-traumatic lower extremity amputations, and end-stage renal disease. Results of the Diabetes Control and Complications Trial have shown that intensive treatment can significantly reduce the debilitating and costly long-term complications associated with the disease. Managing a chronic illness such as DM can best be accomplished by following nationally recognized standards of care such as those published by the American Diabetes Association (ADA). The purpose of this study was to describe the medical management for inmates diagnosed with DM within the FBOP, and compare this to the national standards of care published by the ADA in 1998. To measure adherence to the ADA standards, this descriptive quantitative study utilized the Diabetes Quality Assurance (DQA) Checklist to perform a chart review in a federal prison outpatient clinic. The DQA Checklist major categories include referrals, blood glucose evaluation, diet and exercise, foot care, cardiovascular risk factors, and laboratory tests. Cardiovascular risk factor assessment, cholesterol and triglyceride measurement, nutrition assessment, ophthalmology and ECG referrals were at greater than 87% adherence. However, the degree of adherence was significantly lower in the areas of glycohemoglobin measurement, documented foot exam, HDL and LDL cholesterol measurement.

Key Words: diabetes management in prison adherence to standards inmates

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by

VIRGINIA A. GIROUX, BSN

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CHAPTER I: INTRODUCTION

Background

Diabetes Mellitus (DM) is a chronic progressive disease, which affects approximately 16 million Americans, accounting for 6.2% of the population (Public Health Service, 1998). It is associated with significant morbidity and mortality. Direct and indirect expenses cost the United States \$120 billion annually. Diabetes is the leading cause of blindness and non-traumatic lower extremity amputations in adults (Wood, 1998). In addition, DM is also the leading cause of end-stage renal disease which costs \$1.8 billion per year alone for these patients (Rossing, 1998). Other complications of DM include neuropathy, cardiovascular disease, and peripheral vascular disease. The estimated per capita annual health expenditures in 1992 for non-diabetic people was \$2600 and approximately \$11,000 for diabetic people (Herman, Dasbach, Songer, & Eastman, 1997).

A subset of the U.S. population is the prison population. There were an estimated 1,725,842 people incarcerated in Federal and State prisons and local jails in 1997 (Gilliard & Beck, 1998). Specifically, the Federal Bureau of Prisons (FBOP) had an average inmate population of 105,457 during fiscal year 1998. The amount diagnosed with Type 1 or Type 2 DM is 6039 accounting for 5.7% of the total population. The annual budget of the FBOP, which allows for all aspects of health care, provides \$3364 per inmate (R. Falter, Health Services Division, FBOP, personal communication, January 27, 1999). Medical data gathered from July 1, 1992 to May 31, 1993 documented that 52,622 inmates made 108,406 visits to health services. Diabetes accounted for 20,547 of these visits (FBOP, 1994). With tougher crime laws and mandatory sentencing the result

is an increasingly older inmate population. This means more inmates with chronic and potentially costly illnesses versus the young, essentially healthy inmate population of the 1980s (Thorburn, 1995).

In this era of enormous health care costs the emphasis is on prevention and wellness promotion. The initiation of Healthy People 2000 (Public Health Service, 1991) places the responsibility for maintaining health on the provider and the patient. Results of the Diabetes Control and Complications Trial, has shown that intensive treatment can significantly reduce the debilitating and costly long-term complications associated with the disease (Crofford, 1995). Managing a chronic illness such as DM involves close monitoring and assessments by the provider at regular intervals. This can best be accomplished by following nationally recognized standards of care such as those published by the American Diabetes Association (ADA). The ADA published the clinical recommendations in 1998 defining the minimum medical care that diabetics should receive at every visit with their provider.

Purpose of the Study

Although the ADA has published the standards of care since 1989, there is concern that providers do not follow these recommendations. A chart review conducted at 42 endocrinology clinics revealed deficiencies in all areas except foot care, eye examination, and lipid screening (Stolar, 1995). The fact that providers still may not be adhering to the ADA recommendations in the civilian community leads one to inquire about adherence to these recommendations in a community with potential restrictions such as the FBOP.

This study was significant to nursing because Advanced Practice Nurses (APN) are being increasingly utilized in the FBOP in all areas including out patient clinics and medical centers. APNs are an invaluable part of the health care team in any setting. Traditionally nurses have always placed a strong emphasis on patient education, wellness and disease prevention, and being an advocate for the patient. These areas are the foundation for providing the care needed by diabetics.

Currently, there are no published data on the adherence of ADA recommendations for DM among prison inmates. Therefore, the purpose of this study was to describe the medical management for inmates diagnosed with DM within the FBOP as documented in the inmates charts, and to compare this to a national standard for medical management as set forth by the ADA in 1998.

Research Question

To what extent do health care providers in an outpatient clinic setting of the FBOP meet the standards for basic medical care for medical management of DM during the continuing care visit as set forth by the ADA (1998c). Based on the purpose of the study, the following research questions were addressed:

1. To what extent were referrals to specialists made in the past year as recommended by the ADA guidelines?
2. To what extent was monitoring of diabetes control accomplished by blood glucose evaluation?
3. To what extent did the general care rendered encompass nutrition, physical activity, and diabetes education?

4. To what extent was proper foot care accomplished with a documented foot exam?
5. To what extent were cardiovascular risk factors assessed?
6. To what extent were laboratory evaluations consistent with ADA guidelines?

Conceptual Framework

Providers need to be aware of actual and potential health-related problems within the community they serve in order to provide the best care possible to their patients. The Alliance for Health Model is a model for community assessment, and is intended to serve as a template for health care providers about forces that interact and to provide a composite picture of health and illness in the community (Klainberg, Holzemer, Leonard, & Arnold, 1998).

The first three components of the model, care-management techniques, community-based needs, and influences on resource allocation decisions, are critical aspects of the overall community assessment. These components overlap each other representing the degree of interaction among the elements of the model. Within the specific community being examined the degree of interaction among these components can identify parameters for potential intervention. Encompassing these three components are the mutual aspects of validation of services by the client and expertise of the interdisciplinary team. Arrows going in both directions connecting these two elements represent the mutual importance of both, hence the term alliance (Klainberg et al., 1998).

The FBOP can be considered a community. Providers working in this environment need to be knowledgeable of the regulations governing their institution and

the resources available to render care. The Alliance for Health model can be utilized to assist providers in making appropriate clinical judgements regarding the care their patients receive within their community (Klainberg et al., 1998).

The first component of the Alliance for Health Model is community-based needs which can be derived from many areas. Some examples are patterns of morbidity and mortality, demographics, environmental concerns, and health-related facilities (Klainberg et al., 1998). The inmate population is becoming older with more chronic illnesses leading to higher morbidity and mortality. Twenty-four percent of inmates were between the ages of 35 and 44 in 1996, compared to 12% in 1983 (Harlow, 1998). Consideration must be given to the ramifications of confinement. Inmates may not have the freedom to always make suitable dietary choices or maintain an exercise program, two very important components of DM management.

The second component of the Alliance for Health Model is care-management techniques which can be influenced by variables such as expectations of the public for care, competence of professionals, and accepted standards of care (Klainberg et al., 1998). Inmates can be a challenging population with which to work. They often do not seek medical care while not incarcerated because of lifestyle, personality, and systemic barriers (Conklin, Lincoln, & Flanigan, 1998). The majority of health care providers within the FBOP are licensed and or certified within their specialty. There is an initiative to have all facilities nationally accredited and all medical personnel are appropriately credentialed at present.

The third component of the Alliance for Health Model is influences on resource allocation decisions which can be influenced by variables such as reliance on local,

regional, and federal government funding, and patterns of insurance coverage (Klainberg et al., 1998). The resources for health care rest on the FBOPs annual budget derived from federal funding. Providers need to be prudent in making referrals for specialized care while continuing to provide the standard of care.

The final two components of the Alliance for Health Model are the expertise of the interdisciplinary team and the validation of services by the patient (Klainberg et al., 1998). Within the outpatient clinic setting in the FBOP, there is a physician in charge along with advanced practice nurses and physician assistants providing all aspects of primary care. Inmates are provided health services encompassing initial intake screening, sick call, chronic care clinics, and emergency care 24 hours a day.

This study focused primarily on adherence to the standards of care. Community-based needs, resource allocation decisions and the expertise of the providers were not examined directly, but are important factors in the overall care that inmates receive. The fifth component, validation of services by the patient, was not be utilized in this study. The inmates perception of the care they receive was not studied.

Conceptual and Operational Definitions

For the purpose of this study the following conceptual and operational definitions were used:

Standard Of Care

Standard is defined as That which is established by custom or authority as a model, criterion, or rule for comparison of measurement (Thomas, 1985, p. 1616). This study will compare the medical management inmates with DM receive with the ADA guidelines for continuing care visits.

Providers

Any physician, advanced practice nurse, or physician assistant that is utilized by the FBOP to provide medical care to inmates.

Federal Bureau of Prisons (FBOP)

It is the mission of the FBOP to protect society by confining offenders in the controlled environments of prison and community-based facilities that are safe, humane, cost-efficient, and appropriately secure, and that provide work and other self-improvement opportunities to assist offenders in becoming law-abiding citizens (FBOP, 1998).

American Diabetes Association (ADA)

A nonprofit health organization with more than one million volunteers including physicians, scientists, nurses, dietitians, pharmacists, social workers, and educators dedicated to the prevention and cure of diabetes (ADA, 1999).

Diabetes Mellitus (DM)

For the purposes of this study both Type 1 and Type 2 are inferred with the term Diabetes Mellitus unless otherwise noted. Type 1 DM (formerly referred to as juvenile onset and Type I) is a classification of diabetes mellitus characterized by Beta-cell destruction that may be immune mediated or idiopathic with absolute insulin deficiency. Type 2 DM (formerly referred to as mature onset and Type II) is a second classification of DM characterized by insulin resistance with relative insulin deficiency that may or may not require exogenous insulin (Wood, 1998).

Referrals

Referrals to appropriate specialists are an important component in DM management (ADA, 1998c). This were operationally measured by documentation of the following:

1. Annual dental examination.
2. Annual dilated eye examination by ophthalmologist or optometrist.
3. Electrocardiogram obtained or referral to cardiologist within the past year.

Blood Glucose Monitoring

Used to measure the level of glycemic control and to make the necessary adjustments in the treatment regimen (ADA, 1998c). This was operationally measured by documentation of the following:

1. Number of times the fasting serum blood glucose obtained over the past year.
2. Number of times the Glycohemoglobin was measured over the past year.

General Care

Areas to be addressed during each continuing care visit (ADA, 1998c). This was operationally measured by documentation of the following:

1. Diet intervention specified.
2. Consult to a Registered Dietitian or nutritionist.
3. Prescription for exercise/physical activity.
4. Diabetes education provided.

Foot Care

A foot examination is required during each continuing care visit (ADA, 1998c).

This was operationally measured by the documentation of the following:

1. The foot exam must consist of at least two of the following elements: skin condition; pulse/vascular; neurological.
2. Referral to podiatry.

Cardiovascular Assessment

Assesses cardiovascular status and identifies abnormalities which may require intervention (ADA, 1998c). This was operationally measured by the documentation of the following:

1. Height, weight, and blood pressure measurement.
2. Smoking cessation.

Laboratory Evaluation

ADA (1998c) guidelines require annual testing for lipid disorders and to identify renal abnormalities. This was operationally measured by the documentation of the following:

1. Annual fasting serum cholesterol, triglyceride, LDL cholesterol, and HDL cholesterol.
2. Urinalysis for protein annually
3. Annual microalbumin measurement if urinalysis is negative for protein.

Limitations

Limitations are restrictions in a study that might decrease the generalizability of the findings (Burns & Grove, 1997). The following are limitations identified in this study:

1. The medical record may not be representative of the care actually rendered by the provider.
2. The institution chosen for this study may not be representative of all institutions within the FBOP. There are several classifications for institutions based on their mission and level of security, which could affect the type of care that inmates receive.
3. A convenience sample was used.

CHAPTER II: REVIEW OF LITERATURE

Introduction

Diabetes affects 5.9% of the population (15.7 million people) with 798,000 new cases diagnosed in the United States (US) each year (National Diabetes Information Clearinghouse [NDIC], 1997). The economic burden of Diabetes Mellitus (DM) in the US continues to be enormous and disproportionate to the number of people affected. Medical, behavioral, and policy changes, and innovations that can prevent or slow the progression of the complications associated with DM can significantly reduce the costs of this disease (American Diabetes Association [ADA], 1998a). This chapter is a review of the literature related to the complications of DM, the prevention of the complications, and providers' adherence to the ADA guidelines.

Theoretical Review

Complications of Diabetes Mellitus

The complications of DM affect numerous body systems and organs and have a significant impact on morbidity and mortality. Coronary artery disease is the leading cause of diabetes-related deaths. (O'Brien, Nguyen, & Zimmerman, 1998). The incidence of peripheral vascular and cerebrovascular disease is also increased among patients with DM. The risk of stroke is 2.5 times higher in those with diabetes and they occur at a younger age. Prevention of stroke requires early recognition and treatment of hypertension, which is the major risk factor (Horvitz & Garber, 1997).

Approximately 60-70% of people with diabetes also have nervous system damage ranging from mild to severe. This includes paresthesia or dysesthesia in the feet or hands, gastroparesis, carpal tunnel syndrome, and various other nerve problems. Severe forms of

nerve damage contribute to lower extremity amputations (NDIC, 1997). Neuropathy combined with arterial insufficiency leads to foot disorders such as ulceration, infection, and gangrene. The complications involving the foot account for hundreds of millions of dollars annually, long hospital stays, and lengthy periods of disability. Of the estimated 16 million people with DM, approximately 15-20% will be hospitalized with a foot complication, and many will require amputation. Prompt and aggressive treatment can often prevent an exacerbation of the problem and the potential need for amputation with early detection being the key (Frykberg, 1998).

DM is also associated with renal disease. Untreated diabetic nephropathy is lethal. An estimated 25% of patients develop this complication after 25 years with diabetes (Rossing, 1998). Constant hyperglycemia causes intraglomerular hypertension and renal hyperfusion, which can eventually lead to renal failure. The primary goal of providers should be prevention to include control of hyperglycemia, hypertension, and dietary restriction of protein and phosphorus when renal function begins to deteriorate (Eaks & Tiszka, 1998).

Another common vascular complication of DM is diabetic eye disease. If changes in the eye are not detected early, it can lead to macular edema (maculopathy) and retinal neovascularization (retinopathy). This represents the leading cause of new cases of blindness among people of working age. Recent studies have shown that the early detection and treatment of retinopathy results in considerable savings (Javitt & Aiello, 1996).

Prevention of Diabetes Mellitus Complications

The Diabetes Control and Complications Trial (DCCT) was a multi-center, randomized clinical trial that compared intensive and conventional diabetes therapy in insulin dependent diabetes mellitus (IDDM) patients. The study examined the effect of each type of therapy on the development and progression of vascular and neurologic complications. Two cohorts of diabetic patients were studied over 6.5 years in order to answer two questions. Will intensive therapy prevent diabetic retinopathy, and will intensive therapy affect the progression of early retinopathy. Although retinopathy was the primary focus for the study, they also studied renal, cardiovascular, neurological, and neuro-psychological outcomes and the adverse effects of the two treatment regimens (Diabetes Control and Complications Trial Research Group [DCCTRG], 1993).

A total of 1441 patients recruited from 29 centers were placed in one of two groups. The primary-prevention group included patients that had no retinopathy at baseline and the secondary-prevention group included patients with mild retinopathy at baseline. Each group was then further divided into either the intensive or conventional therapy group (DCCTRG, 1993).

The intensive therapy group received insulin three or more times daily by injection or insulin pump. The dosages were adjusted according to self-monitored blood glucose performed at least four times daily, dietary intake, and anticipated exercise. The goals of intensive therapy included maintaining a preprandial blood glucose concentration between 70 and 120 mg/dl, postprandial concentration less than 180 mg/dl, a weekly measured three am concentration greater than 65 mg/dl, and monthly hemoglobin A1c

(glycosylated hemoglobin) less than 6.05%. These patients were examined every month and contacted by phone more frequently (DCCTRG, 1993).

The conventional therapy group received one or two daily injections of insulin, daily self-monitored blood glucose, and education about diet and exercise. The goal of conventional therapy was essentially normal growth and development and ideal body weight, and freedom of hyperglycemia. These patients were examined every three months (DCCTRG, 1993).

The incidence of severe hypoglycemia was three times higher in the intensive therapy group than the conventional therapy group. Although there were no deaths, myocardial infarctions, or strokes directly attributable to hypoglycemia there were two fatal motor vehicle accidents, one in each group, in which hypoglycemia may have been a contributing factor. The study found no difference between the two groups in the areas of neuropsychological function or the quality of life questionnaire (DCCTRG, 1993).

The DCCT did show that intensive therapy does slow the progression of retinopathy, nephropathy, and neuropathy by 35-70 percent. Although the risk of hypoglycemia was higher in the intensive therapy group, the benefits outweigh this risk by preventing or slowing the progression of the long-term microvascular and neurological complications (DCCTRG, 1993).

The DCCT did not study patients with non-insulin dependent diabetes mellitus (NIDDM). However, data from epidemiologic studies and clinical trials have shown that hyperglycemia is the cause of diabetic microvascular complications in both insulin dependent and non-insulin dependent diabetes mellitus. Two such studies were the Wisconsin Epidemiologic Study of Diabetic Retinopathy (Klein, Klein, & Moss, 1996),

and the six-year randomized clinical trial of Japanese NIDDM patients (Ohkubo et al., 1995).

Empirical Review

Adherence to ADA Guidelines

A standard of care is the norm on which the quality of care given is judged (Burns & Grove, 1997). Since 1989 the ADA has published their position statement regarding the standards of medical care for diabetics. The standards published by the ADA are intended to define the basic medical care people with diabetes should receive (ADA, 1999). Although the results of the DCCT and other notable studies have demonstrated near normoglycemic levels reduce long-term complications and the ADA publishes standards of care based on this research and the recommendations of many experts, the literature shows that providers are still not adhering to the recommendations of the ADA.

Data can be obtained regarding provider compliance with the ADA standards through one of three methods: provider self-report, patient survey, or medical record review. An extensive chart review done in 1992 measured the quality of care provided to 6,959 diabetic patients followed by the Indian Health Service. Of the charts reviewed, 87% revealed compliance regarding assessment of both weight and blood pressure. Annual urinalysis was measured in 78%, blood glucose levels in 75% (no data regarding GHb), and total cholesterol was measured in 74% of the charts. Lesser compliance was noted with annual funduscopy and comprehensive foot exam with 53% (Mayfield et al., 1994).

The Endocrine Fellows Foundation Study Group examined the implementation of the ADA standards into practice at 42 academic institutions. The data was obtained from

patients' initial assessments and their annual comprehensive evaluations performed in 1989 and 1992-1993. In regards to the initial assessment 31% had no documented diet history and only 34% had a review of exercise habits. Inquiries into a history of hypoglycemia were not done in 22% of patients. During the physical examination nearly one-third did not have an eye examination during the annual visit, and less than 10% had orthostatic blood pressures recorded. Although foot care is a mandatory component, only 74% of patients had a foot examination at their annual visit. More than half the patients studied did not have periodic HbA1c testing, and one-third of the NIDDM patients did not have an annual lipid screening or urinalysis. Despite these numbers, 75% of the programs were assessed to have improved following the publication of the ADA recommendations (Stolar, 1995).

A major health maintenance organization in California conducted its own study to document the quality of care their diabetic patients receive and compare it to the ADA standards. From the 14,539 diabetics identified within their organization 353 charts were randomly selected for review. Glycated hemoglobin (GHb) levels were not documented in 56%, and of those with documented GHb levels 39% had at least one value greater than or equal to 10%. Urine protein measurements were not documented in 52% and foot exams were not done in 94% of the patients. Blood pressure was measured in 86% and 21% of patients had one or fewer visits per year (Peters, Legorreta, Ossorio, & Davidson, 1996).

Another chart review comparing the practice patterns of Nurse Practitioners (NP) in the care of diabetic patients revealed similar findings (Fain & Melkus, 1994). A convenience sample of 78 records of patients under the care of six NPs in an ambulatory

primary-care clinic were reviewed. In this study standards of care were based on four major categories: referrals, glucose evaluation, nutrition, and foot care. The Diabetes Quality Assurance Checklist (Wylie-Rosett, Cypress, & Basch, 1992) was utilized to measure the four major categories. Approximately 50% were referred for ophthalmic examination and/or electrocardiogram and 44% to a registered dietitian. Fifty-seven percent of the records indicated only annual testing of HbA1c and 23% not being tested at all. Furthermore, 32% of records had no evidence of home blood glucose monitoring being recommended or described. The NPs conducted a comprehensive foot examination in only 23% of the patients with a 53.9% referral rate to podiatrists (Fain & Melkus, 1994).

The National Institute of Diabetes and Digestive and Kidney Diseases conducted a nationwide survey of physicians related to the care of diabetic patients. Data was compiled from the 1,434 physicians who provided complete responses to the clinical portion. The majority of the physicians self-reported performing annual funduscopic and 47-80% reported semiannual foot exams. Annual urinalysis testing was lowest with adherence rates 20-39% and annual lipid testing the highest at 90-99% (Kenny, Smith, Goldschmid, Newman, & Herman, 1993).

Larme and Pugh (1998) conducted a study to explore attitudes, rather than knowledge, that may impede primary care provider adherence to standards of care in diabetic patients. The study consisted of 31 primary care providers attending a CME program on diabetes. Providers rated on a 10-point scale how the treatment of diabetes compared to five other chronic conditions: hypertension, hyperlipidemia, angina, arthritis, and heart failure. The scale's rating system was 1=easier to 10=harder and 5.5 being the

midpoint. The providers rated diabetes as significantly harder to treat than hypertension (24 of 30 >5.5) and angina (20 of 30 >5.5). The majority also rated hyperlipidemia (18 of 30) and arthritis (20 of 30) as easier to treat than diabetes.

In a subsequent qualitative interview the providers were asked to explain their scale ratings. The explanations cited by the providers included frustrations with the characteristics of the disease itself and the complexity of its management, and a perceived lack of support from society and the health care system for their efforts to control diabetes (Larme & Pugh, 1998).

Harris (1996) reported on the medical care of diabetic patients with the results of the 1989 National Health Interview Survey (NHIS). This survey is an annual personal interview done in the households of a nationwide sample of the civilian, noninstitutionalized U.S. population. The final sample consisted of 2405 people over 18 years of age who were identified and self-confirmed as having diabetes diagnosed by a physician. Results indicated about 10% did not have a physician for regular care of their diabetes. Sixty-four percent reported following prescribed diet therapy and approximately 65% reported inspecting their feet at least once per week. When asked if they had attended any diabetes program or class 59% of IDDM and 24% of NIDDM patients responded yes. However, almost all reported having received information from some source with physicians accounting for 86%.

Summary

This review provides a baseline for the quality of care that is currently provided to diabetic patients compared to the recommended ADA standards. In all of the studies

there is a gap between the minimum standard of care recommended by the ADA and the care actually rendered to the patients.

The Federal Bureau of Prisons (FBOP) recognizes the need for promoting a healthy lifestyle as well as preventing the complications associated with chronic illnesses such as diabetes (FBOP 1994). At present, the two main sets of standards for prison health care are the American Correctional Association (ACA) and the National Commission on Correctional Health Care (McDonald, 1995). The FBOP institutions are accredited by the ACA and specifically the individual health services units are accredited by the Joint Commission for Accreditation of Hospital Organizations.

The ADA (1998b) also publishes recommendations regarding the management of diabetes in correctional institutions. The ADA states people with diabetes in correctional institutions should receive care equivalent to all people with diabetes. Studies comparing the medical care of diabetic inmates in the U.S. similar to those discussed here have not been conducted. Given the unique circumstances within prison, one cannot assume the results would be the same.

CHAPTER III: METHODOLOGY

Research Design and Procedures

This study used a descriptive quantitative design to measure the adherence to the national standards of care for diabetes management as published by the ADA in 1998. Data regarding this project was obtained by retrospectively examining statistical variables contained in the medical files of inmates who met certain criteria. The data was collected at a Federal Prison outpatient clinic in January/February, 2000. The Health Services Department at the chosen institution generated a list of all inmates currently confined in the outpatient clinic with a diagnosis of Type 1 or Type 2 Diabetes Mellitus. The medical records of the sampled inmates were obtained and reviewed by this researcher for inclusion/exclusion criteria and completion of the checklist. The instrument that was utilized in this study was the Diabetes Quality Assurance (DQA) Checklist (see Appendix A) developed by Wylie-Rosett, Cypress, & Basch (1992). The anticipated result of this study was that it would indicate a satisfactory level of care as compared to the national standards of care published by the ADA in 1998. The medical records were reviewed within the confines of the chosen facility and did not leave the institution.

Sample

The convenience sample was derived from inmates confined within the outpatient clinic of the chosen institution. Subjects who met the following inclusion criteria were included in the sample: (a) the subject must have a diagnosis of Diabetes Mellitus Type 1 or 2 for at least one year, (b) the subject must have received primary care regarding their diabetes treatment from a Physician, Physicians Assistant, or Advanced Practice Nurse. Subjects who met the following exclusion criteria were not included in the sample: (a)

any subject who was hospitalized for the management of diabetes in the previous six months, (b) any subject with a current release date of less than one year remaining to serve on their sentence.

The number of inmates with a diagnosis of Type 1 or Type 2 DM was 70 and the final sample size included those inmates who met the inclusion and exclusion criteria. One hundred percent of all inmates who met the above criteria within the selected facility were included in the study for a final sample size of 62.

Measurement

This study utilized the Diabetes Quality Assurance (DQA) Checklist developed by Wylie-Rosett, Cypress, & Basch (1992) to measure adherence to the ADA Standards of Medical Care (1998c) over a one-year period of time. The DQA Checklist originally contained two sections: a Basic Assessment and a High Risk Assessment and Intervention. This study only utilized the Basic Assessment portion. Written permission to use this tool was obtained from Dr. Wylie-Rosett (see Appendix B).

Face validity of the instrument was established by Wylie-Rosett et al. (1992) using a panel of seven diabetic experts which reviewed the items on the DQA Checklist, the scores assigned to each item, and the chart-review protocol. The reliability was then established using sample charts selected from two separate locations, a primary care clinic and a Diabetes Research and Training Center, both located in New York, New York. The chart reviews were conducted by graduate students who did not have clinical experience related to diabetes. Scores obtained from two reviewers at the same point in time were compared for inter-rater reliability. The scoring of the same charts by the same reviewer at two different times were compared for intra-rater reliability.

To ensure the content validity for this study the DQA Checklist and the research questions were reviewed independently by two experts in DM. Both are Masters prepared Adult Nurse Practitioners currently practicing in diabetes management. The individual elements were rated for the degree of relevance to the purpose of the study. Both experts rated each element as relevant or very relevant with a result of 1.00. In addition, comments by the experts were reviewed for relevance to this study, but did not modify the tool in any way. The comments either reinforced the data already to be collected or were aimed at treatment measures, which was not the purpose of this study. Intra-rater reliability was also measured again for this study. The first ten records were reviewed a second time at the end of the data collection period and resulted in a 99% agreement.

The instrument was comprised of six sections with points being assigned to the individual elements for each yes response. A yes was marked and points given based on documentation in the medical record for that element. The DQA Checklist had a maximum score of 92 based on the following scores by category: 16 points for referrals to specialists, 20 points for glucose monitoring, 20 points for general health care, 15 points for foot care, 9 points for cardiovascular assessment, and 12 points for laboratory tests related to complications. The first section evaluated the use of referrals to dental, ophthalmology, and cardiology. The next section reviewed blood glucose and glycohemoglobin measurement. The third section reviewed the general care given regarding nutrition, exercise, and diabetes education. The three remaining sections evaluated foot care, assessment of cardiovascular risk factors, and laboratory tests. Cardiovascular risk factors were assessed by the measurement of weight, height, blood pressure, and smoking habits. The annual laboratory tests specifically required were

cholesterol, HDL cholesterol, LDL cholesterol, triglycerides, urinary protein, and a microalbumin if the urinary protein is negative.

The point value portion of the DQA Checklist was not utilized for this study for two major reasons. The first reason involves the lack of actual requirement by the ADA (1998) to accomplish all of the elements from the DQA Checklist during the continuing care visit. An example of this is the blood glucose measurement which is optional. The second reason was that while all of the elements were found to be important components of diabetes care, some elements were more crucial than others in reducing the overall morbidity and mortality. Therefore, an individual score might be high even if areas such as lipid profile or foot examination were not accomplished.

Protection of Human Rights

A copy of this research proposal was submitted for approval to the Institutional Review Board, Research Administration at the Uniformed Services University of the Health Sciences (see Appendix C) prior to the initiation of the study. Once this approval was obtained in writing, permission from the Federal Bureau of Prisons was then requested and granted (see Appendix D).

Measures were taken to ensure the confidentiality of information on the subjects included in this study. No names or identifying characteristics were reported to ensure anonymity of the subjects selected. This study measured the presence or absence of documentation regarding diabetes management but not the actual treatment that the subjects have received. Data regarding individual subjects was not included in the results as all data was reported in the aggregate form. The medical records were not removed

from the chosen facility and the name of the institution selected remained anonymous. In addition, the identity of the providers was maintained in a confidential manner.

Summary

This study was conducted utilizing a retrospective descriptive design to assess the adherence to the National Standards ascribed by the ADA for DM in 1998. Data were obtained in relation to selected criteria utilizing a chart review of inmates incarcerated in a Federal Prison.

CHAPTER IV: ANALYSIS OF DATA

Description of Final Sample

The purpose of this study was to describe the medical management for inmates diagnosed with DM within the FBOP as documented in the inmates charts, and compare this to a national standard for medical management as set forth by the ADA (1998c). This chapter presents a description of the sample, demographics, and documentation of the use of specific guideline recommendations by the ADA (1998c). These recommendations include referrals, blood glucose and glycohemoglobin measurement, diet and exercise intervention, foot exam, cardiovascular risk factor assessment, and laboratory measurement. A discussion of the final sample will be presented first.

The total population was 100% male and consisted of 70 inmates in the outpatient setting with a diagnosis of DM type 1 or 2. Of the 70 records 62 met the established criteria described under methodology. The final sample of 62 resulted in 5% type 1 and 95% type 2 DM. The ages ranged from 30 to 77 with a mean of 56 years. The number of years with a diagnosis of DM was 1 to 56 with a mean of 11 years. Provider type was noted as anyone providing direct care related specifically to the management of the inmates diabetes (see Figure 1). APNs provided 6% and a PA and/or MD provided 94% of the care.

Presentation, Analysis and Interpretation of Data

Once the checklists were completed the data was entered into the computer and analyzed using the SPSS (Statistical Product and Service Solutions) Software Program. A summary of the statistical results (reported in means, percents and frequencies) is provided demonstrating the degree of adherence to the ADA Standards of Care (1998c).

Referrals

Eighty-seven percent of the records had documentation of either a referral or the actual exam for ophthalmology (see Table 1). Eighty-nine percent had documentation of either an electrocardiogram or cardiology consult. Five percent had a documented referral to dental.

Blood Glucose and Glycohemoglobin Measurement

One hundred percent of the diabetics had a fasting blood glucose measured over the past year. Five percent was measured 1-3 times while 95% was measured 4 or more times in one year (see Figure 2). Glycohemoglobin is a measurement used to determine long term glucose control. Thirteen percent of the records reviewed did not have a glycohemoglobin measurement for the past year. Thirty-four percent of the records showed a glycohemoglobin measurement of one time and 53% with 2 or more times over the past year (see Figure 3).

General Care

The category of general care encompassed five elements including nutrition, exercise, and diabetes education. Regarding nutrition, 95% of the records had a specific diet intervention documented. Ninety-two percent had a reference to the inmates nutrition by other staff. Seventy-nine percent of the records had a consult to a dietician. Seventy-six percent showed documentation of exercise prescription or assessment of the inmates physical activity. Only 70% of the records had any documentation of diabetes education. This was not limited to any specific time frame and included actual education given or the staff's assessment of any previous education. Documentation was accepted

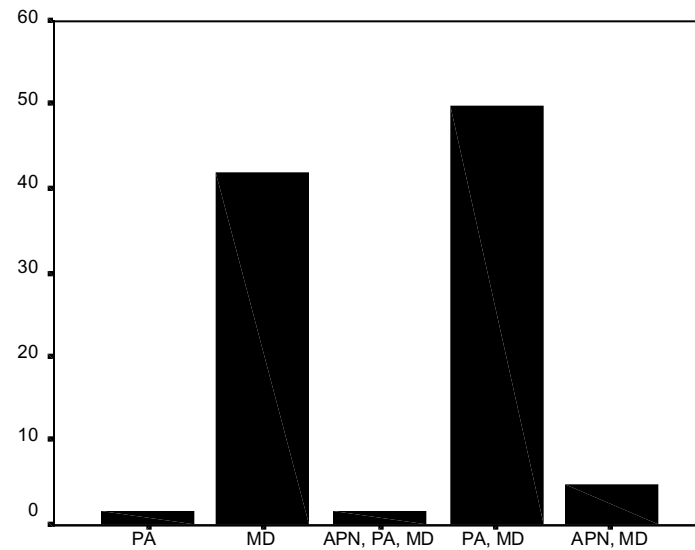


Figure1.

Percentage of Care by Provider Type.

Table 1.

Dental, Opthamology, ECG/Cardiology Referral Performed in the Last Year.

Referral	Yes		No	
	#	%	#	%
Dental	3	5	59	95
Opthalmology	54	87	8	13
ECG/Cardiology	55	89	7	11

N=62

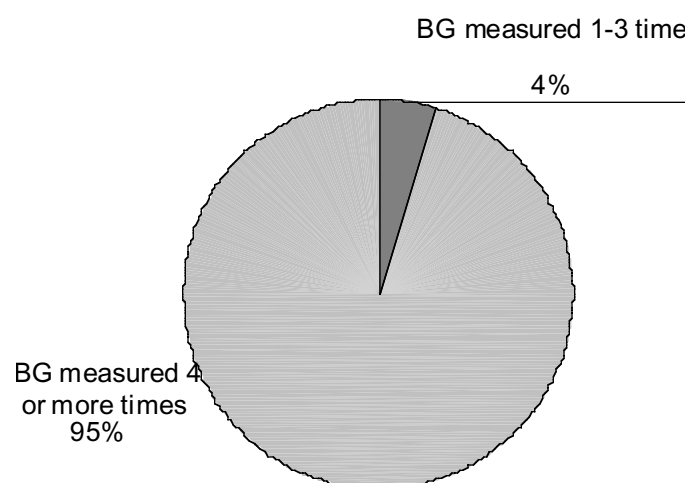


Figure 2.

Percentage of Times Blood Glucose was Measured Over the Past Year.

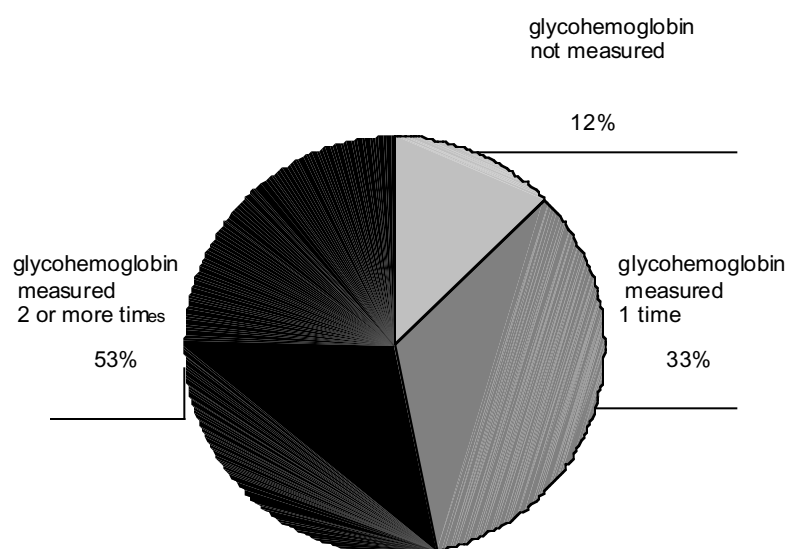


Figure 3.

Percentage of Times Glycohemoglobin was Measured Over the Past Year.

from the physical therapist, dietician, nurses, or primary provider regarding exercise and diabetes education.

Foot Care

In order to receive credit for a foot exam on the DQA Checklist two of the following assessments must have been documented: skin condition, pulse/vascular status, and neurological status. Sixteen percent of the records reviewed had zero and 16 % had one documented foot exam over the past year. However, 66% had two or more foot exams performed. One inmate was noted to have had a bilateral below the knee amputation (see Table 2). The ADA also recommends referral to a podiatrist for problems involving the feet. Only 2% of the records reflected a referral to a podiatrist.

Cardiovascular Risk Factor Assessment

Four elements were evaluated in this category. Weight and blood pressure were routinely documented in 100% of the records reviewed. Likewise, 100% of the inmates had a recorded height and smoking history on their admission paperwork.

Laboratory Test

The ADA recommends that diabetics be tested annually for lipid disorders with serum cholesterol, triglyceride, HDL cholesterol, and LDL cholesterol measurements. Cholesterol and triglyceride measurement was accomplished in 100% of the records. HDL and LDL cholesterol was measured in 50% of the cases (see Table 3). The ADA also recommends that a routine urinalysis be performed annually and if it is negative for protein a test for microalbumin should be done. Ninety-seven percent had a documented urinalysis over the past year. Twenty-three percent were positive for protein. Of the remaining 77%, 37% were tested for microalbumin (see Table 3).

Table 2.**Percentage of Times a Foot Exam was Performed Over the Past Year.**

Foot Exam Performed		
	Frequency	Percentage
Foot not performed	10	16%
Foot exam performed 1 time	10	16%
Foot exam performed 2 or more times	41	66%
Bilateral below the knee amputation	1	2%

N=62

Table 3.**Laboratory Tests Performed to Assess for Lipid Disorders and Urinary Protein.**

Lab Test	Yes		No	
	#	%	#	%
Cholesterol	62	100	0	0
HDL Cholesterol	31	50	31	50
LDL Cholesterol	31	50	31	50
Triglyceride	62	100	0	0
Urinary Protein	60	97	2	3
Urinary Protein Positive	14	23		
Microalbumin	23	37	25	40

N=62

Summary

A total of 62 records were reviewed. Five percent were Type 1 and 95% were Type 2 DM. Eighty-seven percent had an ophthalmology referral, 89% had an electrocardiogram/ cardiology referral, and only 5% had a dental referral over the past year. Ninety-five percent had a fasting blood glucose measurement 4 or more times over one year. Thirty-four percent had a glycohemoglobin measured one time and 53% two or more times over the past year. Ninety-five percent of inmates had a diet intervention specified and 79% had a consult with a dietician. Seventy-five percent had documentation regarding exercise in their record. Eighty-two percent had a foot exam performed one or more times in a year. The height, weight, blood pressure, and smoking assessment were documented in 100% of the records. Likewise, the cholesterol and triglycerides measurements were documented in 100% and a urinalysis documented in 97% of the records. Both HDL and LDL cholesterol were measured in 50% of the subjects over the past year.

CHAPTER V: SUMMARY

Introduction

Diabetes Mellitus affects approximately 16% of the population and leads to significant morbidity and mortality. In all of the studies reviewed there is a gap between the minimum standard of care recommended by the ADA and the care actually rendered to patients. Provided with the unique circumstances within the prison setting, one cannot assume the results would be the same. The purpose of this study was to describe the medical management of inmates diagnosed with DM in the FBOP, and compare it to the standards of care published by the ADA in 1998. Six research questions were investigated during a retrospective chart review of 62 inmates using a quantitative descriptive design.

The population consisted of 70 inmates with a diagnosis of DM. Three were excluded based on less than six months remaining on their sentence and five were excluded based on a diagnosis of less than one year. The remaining 62 records were available and reviewed.

Conclusions

The first research question asked to what extent were referrals to specialists made in the past year. According to the ADA (1998c) a comprehensive dilated eye and visual examination should be performed annually. Eighty-seven percent of the inmates had documentation of a comprehensive dilated eye and visual examination within the past year. One hundred percent of these were based on a referral to and accomplished by an ophthalmologist.

The ADA (1998c) does not specify the need for an ECG for the continuing care of the diabetic patient. However, two panels of diabetic experts concluded that ECGs were

important, therefore, the presence of an ECG over the past year was assessed. Of the 62 records reviewed seven of the inmates did not have a documented ECG over the past year.

The ADA (1998c) recommendations for continuing care does not make reference specifically to an oral examination, but it does recommend assessment of all aspects of self care at each regular visit. Within the FBOP system an inmate undergoes an intake screening process every time he or she enters a different institution, regardless of the time intervals. This process reviews the record to verify certain required elements are present. Examples of these elements are a physical examination, medical history, and certain laboratory tests. The dental department has its own intake screening process and these records are separate from the medical record. Inmates are allowed to go directly to dental to request preventative and restorative services without a referral from medical. Only three of the records documented assessment of the inmates oral hygiene and each of these recommended the inmate seek dental treatment.

The institution selected for this study has its own foot care clinic staffed by a PA. Inmates are evaluated and treated in this clinic for their foot care needs. An inmate is only referred to a Podiatrist whenever surgery is necessary. Only one inmate received a referral to a podiatrist during the past year.

The second question addressed the monitoring of diabetes control determined by blood glucose measurement. The ADA (1998c) recommendations recommend a glycohemoglobin at least twice a year for patients who are stable and meeting goals and quarterly for those who are not. This is a measurement of long term glycemic control. Only fifty-three percent of the inmates had a glycohemoglobin measured two or more

times over the past year. Two inmates had just arrived at this institution within the past six months and their medical records had not been transferred as of yet. Another five inmates had only been in the FBOP for three months or less, and had either one or no glycohemoglobin measurement. However, this still leaves 22 inmates that did not meet the minimum recommendations.

The measurement of fasting plasma glucose is optional in the ADA (1998c) recommendations for continuing care visits. However, 100% of the inmates had a blood glucose measurement at least once over the past year, and 95% had it done four or more times.

The third question asked if the general care rendered encompassed nutrition, physical activity, and diabetes education. A specific diet intervention was ordered for 59 of the inmates. Seventy-nine percent had a written consultation with a dietician. Fifty-seven records contained documentation by other staff regarding nutrition. In 70% of the records documentation existed either assessing past diabetes education received or providing education to the inmate. Credit was given for diabetes education from their provider, dietician, or physical therapist. Seventy-six percent had documentation of the inmates physical activity.

The fourth question asked to what extent was a proper foot exam accomplished. The ADA (1998c) recommendation for continuing care visits is that a foot exam be accomplished at every regular visit. For this study credit was given for a foot exam which consisted of at least two of the following components: skin condition; pulse/vascular; neurological status. Sixty-six percent had a documented foot exam two or more times and 16% one time over the past year. The majority of the inmates were seen numerous times

in the foot care clinic for diabetic shoes fitting, assessment or treatment of ulcers and various other issues, but again credit was only given for the documentation of the above components.

The last two questions addressed assessment of cardiovascular risk factors and laboratory evaluations. Assessment of cardiovascular risk factors included height, weight, blood pressure and smoking status and was accomplished in 100% of the records. All of these elements were documented on the nursing intake flow sheet. Weight and blood pressure were then also documented at regular visits.

The ADA (1998c) recommends that all adult diabetic patients be tested annually for lipid disorders including cholesterol, triglyceride, HDL cholesterol, LDL cholesterol and have a routine urinalysis performed. The results showed 100% had the cholesterol and triglyceride evaluated but only 50% had the HDL and LDL cholesterol measurement. Ninety-seven percent had a urinalysis performed. If the urinary protein is negative on the urinalysis the recommendations require a microalbumin be measured. Of the 77% that tested negative only 37% had the microalbumin measured.

Although there are no previous studies examining the adherence to the ADA guidelines within a prison, three studies were discussed in chapter two examining adherence to the ADA standards within the general population. The first study examined the quality of care provided by the Indian Health Service (IHS) in 1992 with a sample size of 6,959 (Mayfield et al., 1994). The second study, conducted by the Endocrine Fellows Foundation Study Group, was in 1993 with a sample size of 790 (Stolar, 1995). The third study, published in 1994, examined the practice patterns of nurse practitioners (NPs) and had a sample size of 78 (Fain & Melkus, 1994). Compared to these three

studies the FBOP showed greater adherence to the ADA standards in all areas except the measurement of glycohemoglobin. The endocrine fellows measured the glycohemoglobin two or more times annually in 82% of the subjects compared to 53% by the FBOP.

Recommendations for Practice

Although the study of one institution limits the generalizability of the results to the entire FBOP, the results showed a significant compliance with the ADA (1998c) recommendations for continuing care visits. The ADA publishes new guidelines annually, which reflect the on-going research aimed at reducing the devastating effects of the disease. Providers need to be diligent in staying up to date by using methods such as continuing medical education and current articles in professional journals.

The providers need to know that appropriate measurement of blood glucose control and other laboratory tests such as a lipid profile or urinalysis can detect abnormalities in a timely manner and may prevent the long-term morbidity associated with DM. Another very important component that needs to be emphasized is providing diabetes education to the patient. Patients themselves are responsible for a large portion of the success or failure of their diabetes management. However, they must receive the information to take an active role in their care.

Additional studies could be done to measure actual treatment provided as a result of various laboratory results or findings on the foot exam. Surveys could be conducted to assess the knowledge of diabetes management among providers in the FBOP.

Summary

Compliance with the standards for medical care published by the ADA (1998c) were noted in several areas. Cardiovascular risk factor assessment, cholesterol and

triglyceride measurement, nutrition assessment, ophthalmology and ECG referrals were at greater than 87% adherence. The study showed a lack of compliance with glycohemoglobin measurement, documented foot exam, HDL and LDL cholesterol measurement. An overall significant conclusion to this study was that provider adherence to the ADA standards of care was either comparable to or greater than in the general population.

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APPENDICES

Appendix A Authorization for Diabetes Quality Assurance Checklist

Appendix B Diabetes Quality Assurance Checklist

Appendix C Memorandum for Institutional Review Board Approval

Appendix D Memorandum for Federal Bureau of Prisons Approval

**ALBERT EINSTEIN COLLEGE OF MEDICINE
OF YESHIVA UNIVERSITY**
JACK AND PEARL RESNICK CAMPUS

Phone: (718) 430-2700
Fax: (718) 430-8780

Mailing Address:
Department of Epidemiology and Social Medicine
Albert Einstein College of Medicine
1300 Morris Park Avenue
Bronx, New York 10461

April 20, 1999

Re: DQA Checklist

Virginia Giroux, LCDR, USPHS
1004 Denvere Road
Silver Springs, MD 20903

Dear Ms. Giroux:

Thank you for your interest in the Diabetes Quality Assurance (DQA) Checklist. I am delighted that you will be using it as a tool in your thesis that will measure adherence to the American Diabetes Standard of Care in the federal prison outpatient- clinic. You have permission to use the DQA checklist for your research as graduate student in the Family Nurse Practitioner program at the Uniformed Services University of the Health Sciences. I think you are addressing an important issue and wish you the best in your research work.

Sincerely,



Judith Wylie-Rosett, EdD, RD

Professor and Head
Division of Nutrition and Health Promotion
Department of Epidemiology and Social Medicine
Director of the Demonstration and Education Division
Diabetes Research and Training Center

APPENDIX B

Diabetes Quality Assurance Checklist

1. Age: *Missing data=0

2. Diagnosis: 1=Type 1 DM 2=Type 2 DM

3. Number of years diagnosed:

4. Provider type: 1=APN 2=PA 3=MD 4=other

5. Referrals made in past year

Dental	Y	N	(3 pts)
Ophthalmology	Y	N	(10 pts)
ECG/Cardiology	Y	N	(3 pts)

6. Monitoring/Blood Glucose Evaluation

Over the past year, blood glucose measured			
1-3 times	Y	N	(5 pts)
4+ times	Y	N	(10 pts)
Glycohemoglobin measured			
1 time	Y	N	(5 pts)
2+ times	Y	N	(10 pts)

7. General Care

Diet intervention specified	Y	N	(4 pts)
Nutritionist (RD) consulted	Y	N	(6 pts)
Nutrition noted by other staff	Y	N	(2 pts)
Prescription for exercise/physical activity	Y	N	(4 pts)
Provided/referred for diabetes education	Y	N	(4 pts)

8. Foot Care

Foot exam must consist of at least 2 of the following:
Skin condition; pulse/vascular; neurological

Foot Exam			
1 time per year	Y	N	(5 pts)
2+ times per year	Y	N	(10 pts)
Podiatry referral	Y	N	(5 pts)

9. Assessment of Cardiovascular Risk Factors

Weight measured	Y	N	(2 pts)
Height measured	Y	N	(2 pts)
Blood pressure measured	Y	N	(2 pts)
Assessed smoking	Y	N	(3 pts)

10. Laboratory Tests

Cholesterol	Y	N	(2 pts)
HDL Cholesterol	Y	N	(2 pts)
LDL Cholesterol	Y	N	(2 pts)
Triglycerides	Y	N	(2 pts)
Urinary Protein	Y	N	(2 pts)
Microalbumin if urinary protein negative	Y	N	(2 pts)



UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
F. EDWARD HEBERT SCHOOL OF MEDICINE
4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND 20814-4799



May 27, 1999

MEMORANDUM FOR VIRGINIA A. GIROUX, GRADUATE SCHOOL OF NURSING

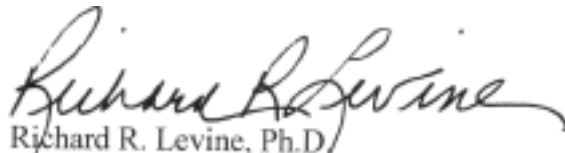
SUBJECT: IRB Approval of Protocol **T06IAH-01** for Human Subject Use

Your research protocol entitled "*A Comparison of Diabetes Management in a Federal Prison with the National Standards of Care Published by the ADA in 1998*," was reviewed and approved for execution on 5/27/99 as an **exempt** human subject use study under the provisions of 32 CFR 2 19.10 1 (b)(4). This approval will be reported to the full IRB scheduled to meet on June 10, 1999.

The purpose of this study is to describe the medical management for inmates diagnosed with Diabetes Mellitus (DM) within the Federal Bureau of Prisons (FBOP) and compare this to the national standards of care published by the ADA in 1998. This study will use the Diabetes Quality Assurance (DQA) Checklist to perform a chart review in a federal prison outpatient clinic. The IRB understands that no prisoner names or identifying information will be collected as part of this study and study results will be used only to demonstrate the degree of adherence to ADA standards of care.

To complete our files for this protocol, please provide this office with a copy of the study approval letter from the Federal Bureau of Prisons once it is received.

Please notify this office of any amendments you wish to propose and of any untoward incidents which may occur in the conduct of this project. If you have any questions regarding human volunteers, please call me at 301-295-3303.


Richard R. Levine, Ph.D.
ITC, MS, USA
Director, Research Programs and
Executive Secretary, IRB

Cc: Director. Grants Administration



U.S. Department of Justice

Federal Bureau of Prisons

Washington, DC 20534

February 2, 2000

MEMORANDUM FOR G.L. HERSHBERGER, REGIONAL DIRECTOR
NORTH CENTRAL REGION

Thomas R. Kane

FROM: Thomas R. Kane, Assistant Director
Information, Policy, and Public Affairs Division

SUBJECT: Research Proposal of Virginia Giroux

This is in response to a request by Virginia Giroux, Graduate School of Nursing, Uniformed Services University of the Health Sciences, to conduct a research project at FMC Rochester entitled "A Comparison of Diabetes Management in a Federal Prison with the National Standards of Care Published by the ADA in 1998."

We concur with your recommendation for approval, and Lieutenant Commander Giroux is authorized to proceed with her study, subject to the capability of the institution to accommodate her.

Any questions that arise may be directed to Gerry Gaes, Chief, Office of Research and Evaluation, at (202) 307-3871, ext. 115.

cc: Constance Reese, Warden, FMC Rochester
Steve Norton, Chair, Local Research Review Board, FMC
Rochester
✓ Virginia Giroux, USUHS